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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1350]

Draft Guidance for Industry on Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients.'' FDA's Center for Drug Evaluation and Research is issuing this draft guidance for drug products in the combined oral contraceptives class. When finalized, the guidance should result in uniform labeling among combined oral contraceptive products. Uniform labeling is important to physicians and patients when they read and try to understand efficacy claims and safety risks associated with drug products in this class. In addition, this draft guidance is intended to provide sponsors of new combined oral contraceptive drug products with a labeling template.

DATES: Submit written comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the

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guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4260.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients.'' The draft guidance is intended to produce uniform labeling among combined oral contraceptive products. Uniform labeling is important to physicians and patients in understanding efficacy claims and safety risks associated with drug products in this class. The draft guidance, which outlines recommendations for the physician insert, also includes a labeling template for physician labeling and instructions for use that can be used for new drug applications and abbreviated new drug applications. Among the labeling recommendations is a black box warning explaining the increased risk of serious cardiovascular side effects associated with the concomitant use of cigarettes and combined oral contraceptives. Once the draft guidance is finalized, the recommended text should be included in all approved, pending, and future applications. This labeling guidance is intended to supersede the ''Labeling Guidance for Combination Oral Contraceptives, Physician and Patient Labeling,'' revised in August 1994.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on combined oral contraceptive labeling for healthcare providers and patients. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that

individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are

available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/28/00
June 28, 2000

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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